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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,515	03/22/2004	Tom F. Lue	220022001610	3893

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MORRISON & FOERSTER LLP  
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SUITE 100  
SAN DIEGO, CA 92130-2040

EXAMINER

QIAN, CELINE X

ART UNIT PAPER NUMBER

1636

DATE MAILED: 07/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/806,515	<b>Applicant(s)</b> LUE ET AL.	
	<b>Examiner</b> Celine X. Qian Ph.D.	<b>Art Unit</b> 1636	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

Claims 1-22 are pending in the application.

#### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5, 9, 11-15 and 21 drawn to a method of preventing or treating male erectile dysfunction or female sexual arousal disorder by administering VEGF protein, classified in class 424, subclass 198.1.
- II. Claims 1-8, 10-15 and 22, drawn to a method of preventing or treating male erectile dysfunction or female sexual arousal disorder by administering nucleic acid encoding VEGF, classified in class 514, subclass 44.
- III. Claims 1-5, 11-15, drawn to a method of preventing or treating male erectile dysfunction or female sexual arousal disorder by administering an enhancer for VEGF expression, classified in class 536, subclass 24.5.
- IV. Claims 1-5, 11-15, drawn to a method of preventing or treating male erectile dysfunction or female sexual arousal disorder by administering an enhancer for VEGF function, classified in class 424, subclass 130.1.
- V. Claims 16-18 and 20, drawn to a combination for preventing or treating male erectile dysfunction or female sexual arousal disorder comprising an agent that stimulates male erectile or female sexual function and one or more of VEGF protein, classified in class 530, subclass 399.
- VI. Claims 16-18 and 20, drawn to a combination for preventing or treating male erectile dysfunction or female sexual arousal disorder comprising an agent that

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stimulates male erectile or female sexual function and one or more of nucleic acids encoding VEGF, classified in class 435, subclass 320.1.

VII. Claims 16-18 and 20, drawn to a combination for preventing or treating male erectile dysfunction or female sexual arousal disorder comprising an agent that stimulates male erectile or female sexual function and one or more agent that enhances VEGF production, classified in class 536, subclass 24.5.

VIII. Claims 16-18 and 20, drawn to a combination for preventing or treating male erectile dysfunction or female sexual arousal disorder comprising an agent that stimulates male erectile or female sexual function and one or more agent that enhances VEGF function, classified in class 424, subclass 130.1.

IX. Claim 19, drawn to a method for preventing or treating male erectile dysfunction or female sexual arousal disorder by administering a combination comprising an agent that stimulates male erectile or female sexual function and one or more of VEGF protein, classified in class 424, subclass 198.1.

X. Claim 19, drawn to a method for preventing or treating male erectile dysfunction or female sexual arousal disorder by administering a combination comprising an agent that stimulates male erectile or female sexual function and one or more nucleic acids encoding VEGF protein, classified in class 514, subclass 44.

XI. Claim 19, drawn to a method for preventing or treating male erectile dysfunction or female sexual arousal disorder by administering a combination comprising an agent that stimulates male erectile or female sexual function and one or more agent that enhances VEGF production, classified in class 536, subclass 24.5.

- XII. Claim 19, drawn to a method for preventing or treating male erectile dysfunction or female sexual arousal disorder by administering a combination comprising an agent that stimulates male erectile or female sexual function and one or more agents that enhances VEGF function, classified in class 424, subclass 130.1.
- XIII. Claims 1-5, 9, 11-15 and 21 drawn to a method of preventing or treating male erectile dysfunction or female sexual arousal disorder by administering BDNF protein, classified in class 424, subclass 198.1.
- XIV. Claims 1-8, 10-15 and 22, drawn to a method of preventing or treating male erectile dysfunction or female sexual arousal disorder by administering nucleic acid encoding BDNF, classified in class 514, subclass 44.
- XV. Claims 1-5, 11-15, drawn to a method of preventing or treating male erectile dysfunction or female sexual arousal disorder by administering an enhancer for BDNF expression, classified in class 536, subclass 24.5.
- XVI. Claims 1-5, 11-15, drawn to a method of preventing or treating male erectile dysfunction or female sexual arousal disorder by administering an enhancer for BDNF function, classified in class 424, subclass 130.1.
- XVII. Claims 16-18 and 20, drawn to a combination for preventing or treating male erectile dysfunction or female sexual arousal disorder comprising an agent that stimulates male erectile or female sexual function and one or more of BDNF protein, classified in class 530, subclass 399.
- XVIII. Claims 16-18 and 20, drawn to a combination for preventing or treating male erectile dysfunction or female sexual arousal disorder comprising an agent that

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stimulates male erectile or female sexual function and one or more of nucleic acids encoding BDNF, classified in class 435, subclass 320.1.

- XIX. Claims 16-18 and 20, drawn to a combination for preventing or treating male erectile dysfunction or female sexual arousal disorder comprising an agent that stimulates male erectile or female sexual function and one or more agent that enhances BDNF production, classified in class 536, subclass 24.5.
- XX. Claims 16-18 and 20, drawn to a combination for preventing or treating male erectile dysfunction or female sexual arousal disorder comprising an agent that stimulates male erectile or female sexual function and one or more agent that enhances BDNF function, classified in class 424, subclass 130.1.
- XXI. Claim 19, drawn to a method for preventing or treating male erectile dysfunction or female sexual arousal disorder by administering a combination comprising an agent that stimulates male erectile or female sexual function and one or more of BDNF protein, classified in class 424, subclass 198.1.
- XXII. Claim 19, drawn to a method for preventing or treating male erectile dysfunction or female sexual arousal disorder by administering a combination comprising an agent that stimulates male erectile or female sexual function and one or more nucleic acids encoding VEGF protein, classified in class 514, subclass 44.
- XXIII. Claim 19, drawn to a method for preventing or treating male erectile dysfunction or female sexual arousal disorder by administering a combination comprising an agent that stimulates male erectile or female sexual function and one or more agent that enhances VEGF production, classified in class 536, subclass 24.5.

- XXIV. Claim 19, drawn to a method for preventing or treating male erectile dysfunction or female sexual arousal disorder by administering a combination comprising an agent that stimulates male erectile or female sexual function and one or more agents that enhances BDNF function, classified in class 424, subclass 130.1.
- XXV. Claims 1-5, 9, 11-15 and 21 drawn to a method of preventing or treating male erectile dysfunction or female sexual arousal disorder by administering bFGF protein, classified in class 424, subclass 198.1.
- XXVI. Claims 1-8, 10-15 and 22, drawn to a method of preventing or treating male erectile dysfunction or female sexual arousal disorder by administering nucleic acid encoding bFGF, classified in class 514, subclass 44.
- XXVII. Claims 1-5, 11-15, drawn to a method of preventing or treating male erectile dysfunction or female sexual arousal disorder by administering an enhancer for bFGF expression, classified in class 536, subclass 24.5.
- XXVIII. Claims 1-5, 11-15, drawn to a method of preventing or treating male erectile dysfunction or female sexual arousal disorder by administering an enhancer for bFGF function, classified in class 424, subclass 130.1.
- XXIX. Claims 16-18 and 20, drawn to a combination for preventing or treating male erectile dysfunction or female sexual arousal disorder comprising an agent that stimulates male erectile or female sexual function and one or more of bFGF protein, classified in class 530, subclass 399.
- XXX. Claims 16-18 and 20, drawn to a combination for preventing or treating male erectile dysfunction or female sexual arousal disorder comprising an agent that

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stimulates male erectile or female sexual function and one or more of nucleic acids encoding bFGF, classified in class 435, subclass 320.1.

XXXI. Claims 16-18 and 20, drawn to a combination for preventing or treating male erectile dysfunction or female sexual arousal disorder comprising an agent that stimulates male erectile or female sexual function and one or more agent that enhances bFGF production, classified in class 536, subclass 24.5.

XXXII. Claims 16-18 and 20, drawn to a combination for preventing or treating male erectile dysfunction or female sexual arousal disorder comprising an agent that stimulates male erectile or female sexual function and one or more agent that enhances bFGF function, classified in class 424, subclass 130.1.

XXXIII. Claim 19, drawn to a method for preventing or treating male erectile dysfunction or female sexual arousal disorder by administering a combination comprising an agent that stimulates male erectile or female sexual function and one or more of bFGF protein, classified in class 424, subclass 198.1.

XXXIV. Claim 19, drawn to a method for preventing or treating male erectile dysfunction or female sexual arousal disorder by administering a combination comprising an agent that stimulates male erectile or female sexual function and one or more nucleic acids encoding bFGF protein, classified in class 514, subclass 44.

XXXV. Claim 19, drawn to a method for preventing or treating male erectile dysfunction or female sexual arousal disorder by administering a combination comprising an



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agent that stimulates male erectile or female sexual function and one or more agent that enhances bFGF production, classified in class 536, subclass 24.5.

XXXVI. Claim 19, drawn to a method for preventing or treating male erectile dysfunction or female sexual arousal disorder by administering a combination comprising an agent that stimulates male erectile or female sexual function and one or more agents that enhances bFGF function, classified in class 424, subclass 130.1.

The inventions are distinct, each from the other because of the following reasons.

The inventions of Groups V-VIII, XVII-XX, XXIX-XXXII are patentably distinct from the inventions of Groups I-IV, IX-XII, XXIII-XXVI, XXI-XXIV, XXV-XXVIII, XXXIII-XXVI because the inventions are drawn to compositions and methods that are not directly related. The methods of Groups I-IV, IX-XII, XXIII-XXVI, XXI-XXIV, XXV-XXVIII, XXXIII-XXVI can be carried out using other compositions rather than the compositions claimed in Groups V-VIII, XVII-XX, XXIX-XXXII, for example, Viagra. Therefore, the inventions of Groups V-VIII, XVII-XX, XXIX-XXXII are patentably distinct from the inventions of Groups I-IV, IX-XII, XXIII-XXVI, XXI-XXIV, XXV-XXVIII, XXXIII-XXVI.

The inventions of Groups V-VIII, XVII-XX, XXIX-XXXII are patentably distinct from each other because the inventions are drawn to materially distinct compositions. The protein, nucleic acid, expression enhancer and functional enhancer of Groups V-VIII, XVII-XX, XXIX-XXXII are biologically, chemically and functional different from each other. Therefore, the inventions of Groups V-VIII, XVII-XX, XXIX-XXXII are patentably distinct.

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The inventions of Groups I-IV, IX-XII, XXIII-XXVI, XXI-XXIV, XXV-XXVIII, XXXIII-XXVI are patentably distinct from each other because the inventions are drawn to methods that require different starting materials and modes of operation. Each method involves different method steps. Therefore, the inventions of Groups I-IV, IX-XII, XXIII-XXVI, XXI-XXIV, XXV-XXVIII, XXXIII-XXVI are patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. A search of the subject matter of one invention would not be co-extensive with a search of the other invention, and therefore the search would be burdensome. Each invention is capable of supporting a separate patent.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

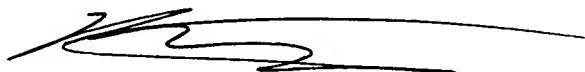
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.  
July 21, 2006

CELINE QIAN, Ph.D.  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to be 'C. Qian', written over a horizontal line.